

REMARKS

Reconsideration of the instant Office Action, entry of the amendments submitted herewith and allowance of all pending claims are respectfully requested.

In the instant Office Action, claims 1, 5-20 and 30-36 are listed as pending, claims 5-8, 10, 12-20 and 30-36 are listed as withdrawn from consideration, claim 1 is rejected, and claims 9 and 11 are objected to.

In response to the instant Office Action, Applicants have amended claim 1. Moreover, in connection with the Examiner's provisional rejection of the subject matter of Group II as set forth in the Requirement for Restriction mailed September 14, 2004, Applicants have amended the specification to add a paragraph in the "Background of the invention" section to more specifically demonstrate the state of the art at the time the present invention was made with respect to the treatment of diseases and medical conditions with compounds having activity at the somatostatin receptor.

Applicants state that the aforementioned amendments do not introduce new matter and that the aforementioned amendments do not require any change of inventorship pursuant to 37 C.F.R. 1.48(b).

1. Applicants are grateful for the Examiner's withdrawal of the finality of the previous Office Action pursuant to 37 C.F.R. §1.114, together with the entry of Applicants' submission of amendments to the claims, a Terminal Disclaimer over co-pending application serial number 10/333,556 and the Information Disclosure Statement, as filed on April 5, 2005.

2. Claims 5-8, 10 and 12-20 remain withdrawn from consideration as not being readable on the elected species and as the Examiner's expanded search has uncovered art anticipating claim 1. In an effort to better restrict the withdrawn claims so as to conform with Applicants' election in response to the restriction requirement as set forth in the Office Action mailed September 29, 2004, claim 1 has been amended to clearly distinguish the claimed compound from the allegedly anticipating prior art compound. Applicants respectfully contend that withdrawn claims 5-8, 10 and 12-20, all of which fall within the definition of elected invention classified by the Examiner as Group I and are dependent on amended claim 1, do not read on unelected subject matter and as matter of right should be rejoined with pending claims 1, 9 and 11.

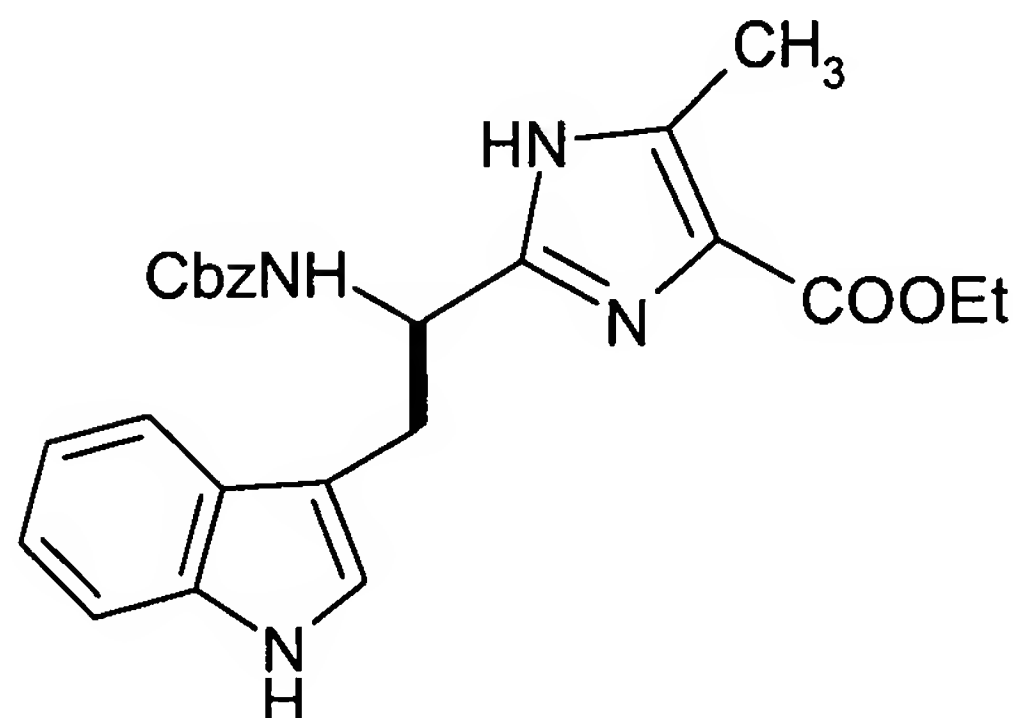
Applicants respectfully request the reconsideration of withdrawal of claims 5-8, 10 and 12-20. Applicants further respectfully request the full examination of amended claim 1 together with withdrawn claims 5-8, 10 and 12-20.

3. Applicants are grateful for the Examiner's reconsideration and withdrawal of the rejection of claim 1 under 35 U.S.C. §102(b) as being anticipated by WO 97/30053 (Gordon *et al.*).

4. Applicants are grateful for the reconsideration and withdrawal of the rejection of claim 1 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-21 of co-pending U.S. Patent Application Serial No. 10/333,556.

5. In the instant Office Action, the Examiner issued *another* double patenting rejection of claim 1 as being unpatentable over claims 2 and 3 of the U.S. Patent No. 6,852,725 (to Thurieu *et al.*). Without conceding the correctness of this rejection and in an effort to solely overcome the provisional rejection of claim 1, Applicants submit a Terminal Disclaimer in compliance with 37 C.F.R. §1.321(c). Applicants respectfully attest that the alleged conflicting Patent, U.S.P.N. 6,852,725, and the above-captioned application have been at all times commonly owned by Societe de Conseils de Recherches et d'Applications Scientifiques, S.A.S., as required under 37 C.F.R. §1.130(b) and that said disclaimer meets all the requirements of 37 C.F.R. §3.73(b).

6. In the instant Office Action, the Examiner issued *another* rejection of claim 1 under 35 U.S.C. §102(b) as being anticipated by von Geldern *et al.*, "Azole Endothelin Antagonists. 1. A Receptor Model Explains an Unusual Structure-Activity Profile," Journal of Medicinal Chemistry, vol. 39(4), pages 957-967 (1996). In support thereof, the Examiner states that "compound 8N" found at page 958 of von Geldern *et al.*, which has the following structure:

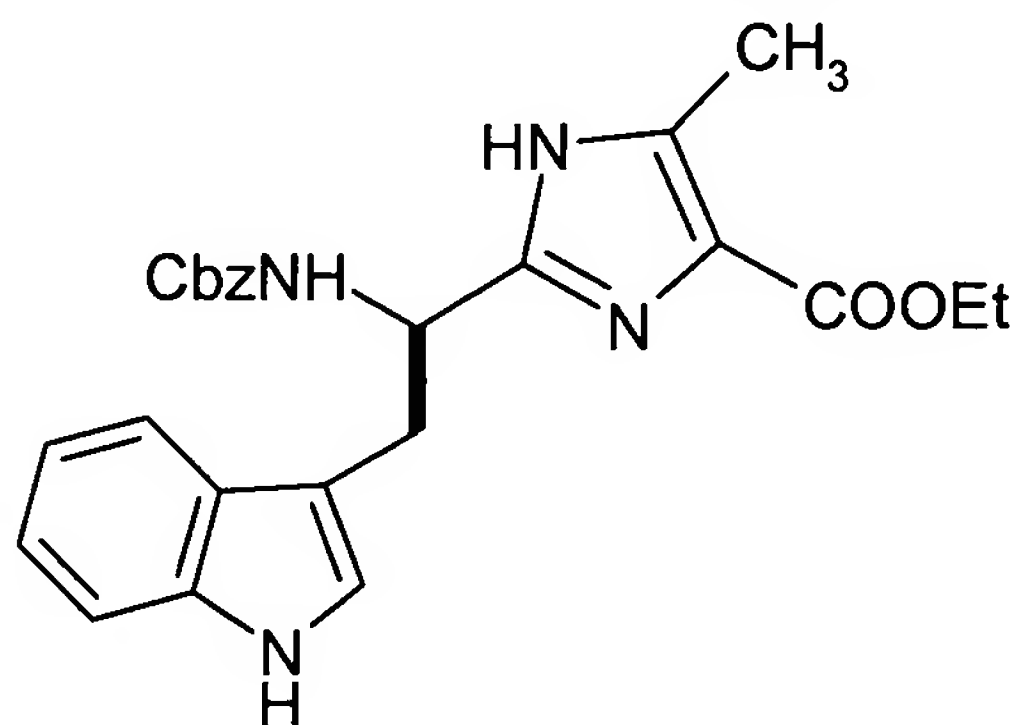


is embraced by instant claim 1,

wherein R^1 is a proton; R^2 is hydrogen; R^3 is $-(CH_2)$ -indol-3-yl; R^4 is $-C(=Y)-X^2$, Y being O, X^2 being $-(CH_2)_m-Y^1-X^3$, with $m=0$, Y^1 is O, X^3 is optionally substituted alkyl, wherein the substituent is $-(CH_2)_m$ -phenyl- X^6 , wherein $m=0$ and $n=1$ and X^6 is hydrogen. The "Cbz" in structure 8 of von Geldern *et al* is benzyloxycarbonyl . . . (See page 5 of the instant Office Action).

In an effort to distinguish the instant application over the cited prior art, Applicants have amended claim 1 by excluding the aforementioned structure as specifically disclosed in von Geldern *et al.* and as specifically cited by the Examiner against the instant claim 1. That is, claim 1 is amended to include the following *proviso* clause:

Provided that the [claimed] compound is not



wherein "Cbz" is benzyloxycarbonyl.

Accordingly, Applicants respectfully request the reconsideration and withdrawal of the rejection of claim 1 under 35 U.S.C. §102(b) as anticipated by von Geldern *et al.*

7. Applicants are grateful for the conditional allowance of claims 9 and 11. Applicants, however, have not amended claims 9 and 11 in independent form including all of the limitations of the base claim and any intervening claims, as directed by the Examiner, in anticipation that base claim 1 has been successfully amended to overcome the rejection thereof. Applicants respectfully request a subsequent opportunity to amend claims 9 and 11, as suggested by the Examiner, in response to a later Office Action or if the rejection of claim 1, as amended above, is maintained.

8. The Examiner indicates that, in the event that claims 9 and 11 are in allowable form, "the subject matter of Group II as set forth in the Requirement for Restriction mailed on 14

September, 2004 will be rejoined, at which time said claims will be the subject of a rejection under the first paragraph of 35 U.S.C. 112, for lack of a disclosure enabling the full scope of what is specified therein.” In response to the Examiner’s express invitation to provide additional material that demonstrates the state of the art at the time the present invention was made with respect to the treatment of diseases and medical conditions with compounds having activity at the somatostatin receptor, Applicants hereby submit copies of the following materials:

- Robbins, R.J., J. Clin. Endocr. Metab., 82:15-17 (1997), in support of the claimed indication of acromegaly;
- Flogstad A.K., et al., J. Clin. Endocr. Metab. 82:23-28 (1997), in support of the claimed indication of acromegaly;
- Caron P., et al., J. Clin. Endocr. Metab. 82:18-22 (1997), in support of the claimed indication of acromegaly;
- Grant, M.B., et al., Circulation, 89:1511-1517 (1994), in support of the claimed indication of restenosis;
- Fedorak, R.N., et al., Can. J. Gastroenterology, 3, No. 2, 53-57 (1989), for the claimed indication of Crohn’s disease;
- Soudah, H., et al., Gastroenterology, 98, No. 5, Part 2, Suppl., A129 (1990), for the claimed indication of systemic sclerosis;
- Hartley, J.E., et al., J. Roy. Soc. Med., 85, pp. 107-108 (1992), for the claimed indication of external and internal pancreatic pseudocysts and ascites;
- Koberstein, B., et al., Z. Gastroenterology, 28, 295-301 (1990), for the claimed indication of VIPoma;
- Christensen, C., Acta Chir. Scand. 155, 541-543 (1989), for the claimed indication of VIPoma;
- Laron, Z., Israel J. Med. Sci., 26, No. 1, 1-2 (1990), for the claimed indication of nesidoblastosis and hyperinsulinism;
- Wilson, D.C., Irish J. Med. Sci., 158, No. 1, 31-32 (1989), for the claimed indication of nesidoblastosis and hyperinsulinism;
- Micic, D., et al., Digestion, 16, Suppl. 1.70. Abs. 193 (1990), for the claimed indication of nesidoblastosis and hyperinsulinism;
- Bauer, W., Europ. J. Pharmacol., 183, 55 (1990), for the claimed indication of gastrinoma;
- Mozell, E., et al., Surg. Gynec. Obstet., 170, 476-484 (1990), for the claimed indication of Zollinger-Ellison Syndrome;

- Cello, J.P., et al., *Gastroenterology*, 98, No. 5, Part 2, Suppl., A163 (1990), for the claimed indication of AIDS related diarrhea;
- Petrelli, N., et al., *Proc. Amer. Soc. Clin. Oncol.*, Vol. 10, P 138, Abstr. No. 417 (1991), for the claimed indication of chemotherapy related diarrhea;
- Soudah, H., et al., *Clin. Res.*, Vol. 39, p. 303A (1991), for the claimed indication of scleroderma;
- O'Donnell, L.J.D., et al., *Aliment. Pharmacol. Therap.*, Vol. 4., 177-181 (1990), for the claimed indication of Irritable Bowel Syndrome;
- Tulassay, Z., et al., *Gastroenterology*, 98, No. 5, Part 2, Suppl., A238 (1990), for the claimed indication of pancreatitis;
- Nott, D.M., et al., *Brit. J. Surg.*, Vol. 77, p. A691 (1990), for the claimed indication of small bowel obstruction;
- Branch, M.S., et al., *Gastroenterology*, Vol. 100, No. 5, Part 2 Suppl., p. A425 (1991), for the claimed indication of gastroesophageal reflux;
- Hasler, W., et al., *Gastroenterology*, Vol. 100, No. 5, Part 2, Suppl., p. A448 (1991), for the claimed indication of duodenogastric reflux;
- Clark, R.V., et al., *Clin. Res.* 38, p. 943A (1990), for the claimed indication of Cushing's Syndrome;
- Ambrosi B., et al., *Acta Endocr. (Copenh.)* 122, 569-576 (1990), for the claimed indication of gonadotropinoma;
- Miller, D., et al., *Canad. Med. Ass. J.*, Vol. 145, pp. 227-228 (1991), for the claimed indication of hyperparathyroidism;
- Chang, T.C., et al., *Brit. Med. J.*, 304, p. 158 (1992), for the claimed indication of Graves' Disease;
- Chan, A.W., et al., *Horm. Res.*, 36:86-87 (1991), for the claimed indication of diabetic neuropathy;
- Palmieri, G.M.A., et al., *J. of Bone and Mineral Research*, 7, (Suppl. 1), p. S240 (Abs. 591) (1992), for the claimed indication of Paget's disease;
- Prelevic, G.M., et al., *Metabolism Clinical and Experimental*, 41, Suppl. 2, pp 76-79 (1992), for the claimed indication of polycystic ovary disease;
- Weckbecker, G., et al., *Pharmac. Ther.*, 60:245-264 (1993), for the claimed indication of cancer;
- Bartlett, D.L., et al., *Surg. Forum.*, 42, pp. 14-16 (1991), for the claimed indication of cancer cachexia;
- Hoeldtke, R.D., et al., *Arch. Phys. Med. Rehabil.*, 69, 895-898 (1988), for the claimed indication of hypotension;

- Kooner, J.S., et al., Brit. J. Clin. Pharmacol., 28, 735P-736P (1989), for the claimed indication of hypotension;
- Hoeldtke, R.D., et al., Am. J. Med., 81:83-87 (1986), for the claimed indication of postprandial hypotension;
- Abelson, J.L., et al., Clin. Psychopharmacol., 10, 128-132 (1990), for the claimed indication of panic attacks;
- Malarkey, W.B., et al., Neuroendocrinology, 49:267-274 (1989), for the claimed indication of GH secreting adenomas or TSH secreting adenomas;
- Dimitriadis, G., et al., Metabolism, 32:987-992 (1983), for the claimed indication of diabetes mellitus;
- U.S. Patent No. 7,026,289, for the claimed indication of hyperlipidemia;
- Orskov, L., et al., Metabolism, 45:211-217 (1996), for the claimed indication of insulin insensitivity;
- U.S. Patent Application No. US-2004-0072734-A1, for the claimed indication of Syndrome X;
- McCombe, M., et al., Eye, 5:569-575 (1991), for the claimed indication of proliferative retinopathy;
- Campbell, P.J., et al., Metabolism, 37:34-37 (1988), for the claimed indication of dawn phenomenon;
- Flyvbjerg, A., et al., Kidney Int., 41:805-812 (1992), for the claimed indication of Nephropathy;
- Kayasseh L, Lancet, 1:844-846 (1980), for the claimed indication of peptic ulcers;
- Nubiola, P., et al., Ann. Surg., 210:56-58 (1989); Erratum in Ann. Surg., 211:246, (1990), for the claimed indication of enterocutaneous fistula;
- Anand, B.S., et al., Am. J. Gastroenterol., 89:267-270 (1994), for the claimed indication of pancreaticocutaneous fistula;
- Hopman, W.P., et al., Ann. Surg., 207:155-159 (1988), for the claimed indication of Dumping syndrome;
- Eriksson, B., et al., Scand. J. Gastroenterol., 23:508-512 (1988), for the claimed indication of watery diarrhea syndrome;
- Buchler, M.W., et al., Gut, 35:S15-S19 (1994), for the claimed indication of acute or chronic pancreatitis;
- Souquet, J.C., et al., Cancer, 59:1654-1660 (1987), for the claimed indication of gastrointestinal hormone secreting tumors;

- Danesi, R., et al., Clin. Cancer Res., 3:265-72 (1997), for the claimed indication of angiogenesis;
- Mantyh, P.W., et al., Peptides, 10:627-645 (1989), for the claimed indication of inflammatory disorders;
- Hayry, P., et al., FASEB J. 7:1055-1060 (1993), for the claimed indication of chronic allograft rejection;
- Yumi, K., et al., Lab. Invest., 76:329-338 (1997), for the claimed indication of angioplasty;
- Rossini, F.P., et al., Am. J. Gastroenterol., 88:1424-1427 (1993), for the claimed indication of gastrointestinal bleeding; and
- Ladas, S.D., et al., Hepatogastroenterology, 45:761-4 (1998), for the claimed indication of inhibiting the proliferation of helicobacter pylori.

In view of the teachings of the above-cited references, Applicants respectfully submit that, as of the time of filing the earliest application from which the present application claims priority, the person of ordinary skill in the art would have known about the treatment of diseases and medical conditions with compounds having activity at the somatostatin receptor. As such, it is respectfully submitted that the Examiner's provisional concern regarding enablement of the claims covering the subject matter of Group II as set forth in the Requirement of September 14, 2004, is obviated.

9. Applicants respectfully request, in the event that the Examiner finds that any of claims 1, 9 or 11 are patentable, the rejoinder of withdrawn claims 30-36 since such claims require the use of patentable subject matter. Under the PTO guidelines for restricting claims covering an apparatus and method of using the apparatus, the examiner must show one-way distinctiveness. See MPEP § 806.05(e). That is, either the apparatus or method must be capable of being practiced without the other. As further noted in MPEP § 821.04:

[I]f Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined . . . Process claims which depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance.

Inventor : Thurieu *et al.*
Serial No. : 10/771,725
Filed : February 4, 2004
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Applicants submit that Claims 30-36 currently incorporate the limitation of Claim 1 by the language "administering a compound according to claim 1" and that the methods of withdrawn claims 30-36 can only be practiced using the patentable subject matter of claim 1. Applicants respectfully contend that the rejoinder of claims 30-36 is appropriate.

Applicants submit that in view of the foregoing remarks, claims 1, 5-20 and 30-36 are seen to relate to a single inventive concept, namely derivatives of imidazolyl, and that such claims are in a form and are of the sort that is properly viewed as relating to a single invention that should not be restricted. Applicants respectfully request that the restriction requirement of the Office Action of September 14, 2004 be reconsidered and withdrawn.

CONCLUSION

Applicants submit that each ground for rejection and objection asserted by the Examiner in the instant Office Action has been removed. On this basis, it is submitted that claims 1, 9 and 11 are now in a condition for allowance. Applicants further request the rejoinder of claims 5-8, 10, 12-20 and 30-36 and submit that said claims are also in a condition for allowance.

Prompt and favorable action is solicited.

Should Examiner Tucker deem that any further action be desirable with respect to these matters, she is requested to telephone the Applicants' undersigned representative.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 50-0590.

Respectfully submitted,

Date:

Oct. 10, 2006

IPSEN/Biomeasure, Incorporated
27 Maple Street
Milford, MA 01757-3650
(508) 478-0144 Telephone
(508) 478-2530 Facsimile



Tony K. Uhm
Attorney for Applicants
Reg. No. 52,450